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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,855	12/29/2003	Leonid A. Kozhemyakin	P0633.70014US01	2748

7590 03/18/2005

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/747,855	<b>Applicant(s)</b> KOZHEMYAKIN ET AL.	
	<b>Examiner</b> Jeffrey E. Russel	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-137 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-137 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2004 and 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/241,232.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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1. The status of the parent application at page 1, lines 8-9, of the specification should be updated.

2. Claims 1-8, 26, 27, 30-35, 37-83, 96, 118-126, 135, and 136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms “oxidized glutathione-based compound” and “glutathione-based compound” in claims 1-4, 26, 27, 30-33, 37, 40-52, 77, 80, and 120 are indefinite. While the term is defined at page 9, lines 14-21, of the specification, this definition relies upon another term, “derivative”, which is itself undefined either in the specification or in the art. It is not clear what constitutes a derivative of glutamic acid, cysteine, or glycine, i.e. it is not clear what structural and/or functional similarity must be present between a compound and glutamic acid, cysteine, or glycine in order for the compound to be considered to be a derivative of glutamic acid, cysteine, or glycine. Given the example of the oxidized glutathione-based compound at page 9, line 22, - page 10, line 9, it does not appear that the derivatives need to be amino acids. As far as can be determined from the discussion of “oxidized glutathione-based compound” at page 9, lines 14-21, all that is required is that the compound comprise a disulfide group and that the compound must be dimeric (which may be inherent due to the presence of the disulfide group). It is believed that claim 6 should instead depend upon claim 5 so that there is clear antecedent basis in the claims for the phrase “the platinum material”. The percentage concentrations set forth in claims 72 and 74 are indefinite because it is not clear what basis, e.g., weight, mole, volume, is to be used to calculate the concentrations. The preamble to claim 77 recites that endogenous production of cytokine and hemopoietic factors is to be enhanced and prolonged. However, claim 77 does not recite any

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process step in which the oxidized glutathione-based compound is administered or contacted with a cell so that the endogenous production can be enhanced and prolonged. Claim 77 only recites the process step of interacting the oxidized glutathione-based compound with a metal material, a step which in and of itself will have no effect on endogenous production. Claim 96 is indefinite because of the phrase "meningitis, sepsis". It is not clear if these two diseases are in the alternative to each other, or if the claim requires the diseases to be treated simultaneously.

3. Claims 48 and 103 are objected to because of the following informalities: At claim 48, lines 2-3, it is believed that "1 about" should be changed to "about 1". At claim 103, line 1, "selected from the group consisting of" should be deleted because only one disease is listed. Appropriate correction is required.

4. Applicants are requested to check the dependencies of claims 118 and 119, which are originally-presented claims but are dependent upon a subsequent originally-presented claim. Should this application pass to issue, the examiner will re-number the dependent claims so that they follow the claim upon which they depend.

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 9-26, 36, 84-95, 97-117, 127-134, and 137 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 9-14, 95-99, 15, 100, 16, 101, 17, 18, 20, 74,

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102-104, 75-79, 105, 80, 81, 83-85, 106, 107, 86-91, 108-117, 124-127, 130-133, and 136,

respectively, of prior U.S. Patent No. 6,312,734. This is a double patenting rejection.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-137 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-136 of U.S. Patent No. 6,312,734.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '734 patent anticipate the instant claims.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

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8. Claims 1, 2, 26, and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Kostic et al. Kostic et al teaches combining  $K_2[PdCl_4]$ , which corresponds to Applicants' metal material, and oxidized glutathione in equimolar amounts. Combining the two components results in the removal of the glycine residues from the oxidized glutathione. See column 12, line 60 - column 13, line 15. Because the resulting peptide compound still has a dimeric structure comprising -Glu-Cys linked by a disulfide bond, the resulting peptide compound is deemed to constitute "an oxidized glutathione-based compound" as claimed by Applicants (but see the rejection under 35 U.S.C. 112, second paragraph, set forth above). Because of the oxidized glutathione's relatively higher molecular weight, even taking into account the hydrolyzed glycine residue, the oxidized glutathione would be present on a weight basis in a ratio of about 1.5:1. Because the reactants and the method steps are the same, inherently the disulfide bonds present in Kostic et al would be stabilized by the palladium compound to the same extent claimed by Applicants, and inherently the ability of the oxidized glutathione-based compound of Kostic et al to stimulate endogenous production of cytokine and hemopoietic factors would be enhanced and prolonged to the same extent claimed by Applicants.

9. Claims 1-8, 27, 30-35, 48-50, 52-57, 59, 60, 68, 71-74, 77, 80-83, 120, 121, 125, 126, 135, and 136 are rejected under 35 U.S.C. 102(e) as being anticipated by Hausheer et al. Hausheer et al teach compositions comprising cisplatin and 2,2'-dithio-bis-ethane sulfonate in an aqueous sodium chloride solution. The compositions are used to treat human patients with cancer such as cancers of the lung, head, neck, ovary, esophagus, bladder, and testis. The weight ratio of the 2,2'-dithio-bis-ethane sulfonate to the cisplatin ranges from about 5:1 to about 1000:1. The concentration of the cisplatin and 2,2'-dithio-bis-ethane sulfonate in the solution can

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be about 1%. The composition is administered by injection. See, e.g., the Abstract; column 2, lines 3-7; column 13, lines 50-65; and the Examples. The 2,2'-dithio-bis-ethane sulfonate, which has a dimeric structure and comprises a disulfide bond, is deemed to constitute "an oxidized glutathione-based compound" as claimed by Applicants (but see the rejection under 35 U.S.C. 112, second paragraph, set forth above). Note that an aqueous solution is capable of being administered topically, and a suggested use limitation does not impart patentability to product claims where the product is otherwise anticipated by or obvious over the prior art. Because the same composition is being administered to the same patients in Hausheer et al as is claimed by Applicants, inherently endogenous production of cytokines and hemopoietic factors will be stimulated to the same extent in Hausheer et al as is claimed by Applicants. Because the same components are being interacted by the same method steps in Hausheer et al as is claimed by Applicants, inherently the ability of the 2,2'-dithio-bis-ethane sulfonate to stimulate endogenous production of cytokine and hemopoietic factors will be enhanced and prolonged in Hausheer et al to the same extent claimed by Applicants.

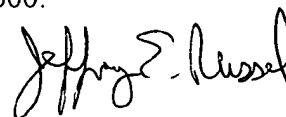
10. Claims 69, 70, 75, 76, 78, 79, 118, 119, 122, 123, and 124 are rejected under 35 U.S.C. 103(a) as being obvious over Hausheer et al. Application of Hausheer et al is the same as in the above rejection of claims 1-8, 27, 30-35, 48-50, 52-57, 59, 60, 68, 71-74, 77, 80-83, 120, 121, 125, 126, 135, and 136. Hausheer et al do not teach Applicants' claimed dosages or dosage rates. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal dosages and dosage rates for the method of Hausheer et al because dosage and dosage rates are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

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11. The examiner maintains his position for the reasons set forth during prosecution of the parent applications.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

March 9, 2005